POSTER No: P080

The Process of Developing a Pharmacovigilance Policy: Experiences from Nigeria and Eswatini

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Introduction

- There is increasing awareness of the importance of medicines safety amongst the population on the African continent
- This calls for a document in the public space specifying roles and responsibilities of Stakeholders within and outside the health sector ensuring, ownership, transparency and inclusiveness in the conversation on Medicine Safety
- The development should be inclusive of the conventional Ministry of Health (MOH), National Medicines Regulatory Authority (NMRA) and Market Authorization Holders (MAH), Patients/Consumers and other Stakeholders
- A Standalone document will obviate the present situation where PV policies are embedded as terse statements in other health and pharmaceutical policy documents
- Its use is likely to strengthen PV with increased reporting of adverse drug events which has been low due to several prevailing factors in resource limited settings.

Objective

- To present a practical outline for use in the development of a PV Policy document.

Methods

Steps in the development of a Pharmacovigilance policy

Advocacy engagement at government level on the need for a policy document as a tool to further strengthen Pharmacovigilance

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Facilitated by a Team of Experts in Pharmacovigilance *[PV Unit (Eswatini)]/Advisory Committee (Nigeria)]*

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Consultation and further preparatory work with the responsible organs of Government including the MOH and the NMRAs

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Identification of multisectoral stakeholders for detailed engagement on various aspects of Pharmacovigilance

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Framework developed [components and provisions for the various elements of the Policy]

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A zero draft was developed by a Lead team and further circulated for clarifications, inputs etc. from other stakeholders

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Call for comments

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Subsequent drafts had the input of other organs of government to avoid conflicts with extant laws and regulations

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Final stakeholder engagement

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Draft forwarded to the requisite statutory organs including the MOH for endorsement

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Approval granted by the National Executive

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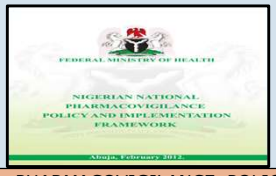
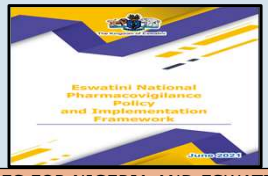
Formal Launch and distribution

Results

- The process was used in the development of PV policy documents for Nigeria [2,3] and Eswatini [4] in 2010 and 2020 respectively.





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Conclusion

- The consensual development of the Policy documents with intense multisectoral stakeholder engagement provides a tool likely to enhance the enabling environment and ensure collaboration of health and non health functionaries in PV activities without undermining statutory laws and regulations.

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Acknowledgement

The development of the Standalone Policy documents took place within the framework of an EDCTP2-funded project PAVIA: PhArmacoVIgilance Africa. and is gratefully acknowledged. The PAVIA project aims to strengthen PV in four African countries: Ethiopia, Nigeria, Swaziland, and Tanzania.

The participation of all Stakeholders and their contribution is noted with due gratitude

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EDCTP
This project is part of the EDCTP2 programme supported by the European Union
PAVIA PhArmaco Vigilance Africa